DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
San Francisco District
Pacific Region
1431 Harbor Bay Parkway
Alameda, CA 94502-7070

Telephone: 510-337-6700
FAX: 510-337-6701

# WARNING LETTER

April 27, 1999

via Federal Express

MQSA Facility ID: 156083
Inspection ID: 1560830005
FDA Reference #: 2951927

Francis Story
Manager, Imaging Services
Diagnostic Imaging - Mercy Medical Plaza
3941 J Street
Sacramento, California 95819

Dear Francis Story,

We are writing to you because on April 15, 1999, your facility was inspected by a representative of the State of California, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 and level 2 findings at your facility:

Level 1: The interpreting physician did not meet the requirement of being certified by an FDA-recognized board or having the alternative of two months training in the interpretation of mammograms: [redacted] {21CFR§900.12(a)(1)(ii)(A)(B)}

Level 2: The interpreting physician did not meet the requirement of having a minimum of forty Continuing Medical Education (CME) credit hours of initial training in mammography: [redacted] {21CFR§900.12(a)(1)(ii)(C)}

Level 2: The interpreting physician did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a six month period): [redacted] {21CFR§900.12(a)(1)(iii)(A)}

Level 2: Mammograms processed with processor 1, room Mammo, operated out of limits on fourteen days at site Diagnostic Imaging - Mercy Medical Plaza. {21CFR§900.12(d)}

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).*

*this note is not applicable for letters which also address patient notification

Please submit your response to:
John M. Doucette, MQSA Inspector/Program Monitor
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, California 94502-7070
510-337-6793 (tel)
510-337-6702 (fax)

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov. If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. John M. Doucette at 510-337-6793.

Sincerely yours,

Patricia C. Ziobro
District Director
San Francisco District Office

cc:
Bonnie Bessemer, MQSA Inspection Program Monitor
State of California
Department of Health Services
Radiologic Health Branch
P.O. Box 942732
601 N. 7th Street, MS-178
Sacramento, California 94234-7320

cc:
Mindy Malone, MQSA Inspector (2184)
State of California
Department of Health Services
Radiologic Health Branch
P.O. Box 942732
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cc:
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